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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,247	07/09/2003	Philip S. Kim	DRPK-0003	9491

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EXAMINER	
STIGELL, THEODORE J	
ART UNIT	**PAPER NUMBER**
3763	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/616,247	KIM, PHILIP S.	
	Examiner	Art Unit	
	Theodore J. Stigell	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 September 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21 and 30-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21 and 30-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-16, 18-21, 30-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Ellinwood, Jr. (3,923,060). Ellinwood discloses a method of providing long term pain management comprising the steps of surgically implanting a catheter to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure (spinal dorsal nerves, sacral ganglia, thoracolumbar ganglia), surgically implanting an implantable pump (150) and reservoir (126) in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site, whereby pain management is provided for weeks, months, or years.

Claims 1-16, 18-21, 30-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Gelfand et al. (US 2005/0192638). Gelfand discloses a method of

providing long term pain management comprising the steps of surgically implanting a catheter (106) to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure (renal nerves), surgically implanting an implantable pump (105) and reservoir (403) in subcutaneous tissue, wherein a proximal end of the catheter, and the reservoir, are in communication with the pump, and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site, whereby pain management is provided for weeks, months, or years.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-16, 18-21, 30-31, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein et al. (Anesth Analg 2000; 91:1473-1478) in view of

Xavier (5,458,631). Klein et al. disclose a method of providing long-term pain management that includes most of the limitations as recited in the claims listed above, including surgically implanting a catheter to create an infusion site, wherein a discharge portion of the catheter lies in a peripheral neural structure, attaching a pump to the catheter and operating the pump to deliver a predetermined dosage of medication through the discharge portion of the catheter into the infusion site. However, Klein et al. teach to use a disposable infusion pump to deliver the drugs instead of an implantable infusion pump. Klein acknowledges that the results of his study demonstrate that it is possible to extend the duration of a peripheral nerve block by using a continuous infusion (See page 1476, first paragraph of Discussion).

Xavier discloses an implantable catheter and pump that provides long term pain management by infusing drugs into the epidural space of the patient. Xavier teaches that it is obvious to use an implantable pump for a continuous infusion to avoid overdosing, for allowing uniform dosing, and to allow the physician to establish anesthesia for surgery as well as the post-operative period (column 2, lines 55-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Klein et al. with the use of an implantable pump of Xavier to make a method of establishing anesthesia for the surgery and post-operative periods that was less prone to complications such as overdosing. The Examiner realizes that claim 37 recites length of time limitations but only in "capable of" language. The Examiner notes that even though Klein does not suggest an infusion of

longer than a couple of days, if Klein was modified with an implantable pump it would be capable of such being implanted for weeks, months, or years.

Claims 17 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (3,923,060) or Gelfand et al. (US 2005/0192638) in view of Elkhoury (5,919,473). Ellinwood and Gelfand disclose a method that includes most of the limitations recited in claim 38 but fail to disclose delivering opiods or antispasmodics or alpha 2 agonists as the pain medication. Elkhoury discloses that delivering opiods to peripheral nerves is effective in reducing pain. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the methods of Ellinwood or Gelfand with the use of opiods as disclosed by Elkhoury to make a more effective method of reducing pain.

Response to Arguments

In response to the Applicant's argument that a prima facie case of obviousness has not been established, the Examiner believes the new rejection now meets all the requirements. The Examiner agrees with the Applicant's argument that it would not be obvious to use opiods or antispasmodics or alpha 2 agonists as the pain medication with the combination Klein and Xavier as these references teach away from using such medications.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 2004/0220545 to Heruth
US 2004/0220543 to Heruth

These references disclose a similar method but do not qualify as prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Theodore J. Stigell whose telephone number is 571-272-8759. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Theodore J. Stigell

Theodore J. Stigell